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## **The need for coronary artery surgery: expand or restrict? a European view**

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So we can actually make only a rough estimate of the costs of the PTCA procedure. From the results of the French registry, one can only estimate, taking into account the costs of the procedure per se, taking into account that in some patients the lesions were not crossed, and these patients were not necessarily treated by bypass surgery, taking into account the rate of emergency, bypass grafting, taking into account the rate of restenosis of 35%, that, within the last 5 years from 1980 to 1985, PTCA has cost in France approx. FF 122 000 000 or approx. \$18 300 000. If we apply the same coefficient of 3 between PTCA and bypass surgery, one can estimate that if these patients had been operated on, the costs would have been FF 360 000 000 or \$55 million. That means that the economy achieved was possibly FF 244 millions or \$36 millions.

If we compare information from eleven centres in France on the respective percentage of the number of PTCA and on the number of bypass grafts per year, we can observe that in 1980, 92% of the patients with suitable lesions for myocardial revascularization have been treated by bypass graft, but in 1985 only 38% of them are being treated by an operation and the greatest number have been treated by PTCA procedure. But if we look to the absolute number of procedures per year, we have a simultaneous increase of the PTCA procedure for the 11 centres and the number of bypass grafts. And this is why I believe that in France and probably in many other countries, it is difficult to convince hospital managers and the Ministry of Health that PTCA is cheaper than coronary bypass surgery.

## **The need for coronary artery surgery: expand or restrict? a European view**

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The aorto-coronary bypass operation, which was introduced during the late nineteen sixties, has become the most efficient treatment of patients with ischaemic heart disease, which causes angina pectoris, heart failure, myocardial infarction or sudden death. During the last 15 years continual improvement of patient selection, surgical techniques, perioperative and postoperative management has resulted in a very low mortality from this operation (comprising 1–2%) and a very high success rate.

Ischaemic heart disease being the most common disease in Western industrial countries and the cost of aorto-coronary bypass being very high, the community represented by public health departments, insurance institutions, politicians, hospital administrators and, last but not least, medical men shows great interest: how big a slice of the resource cake for medical care is taken by aorto-coronary bypass surgery?

### **Benefit and indications for aorto-coronary bypass surgery**

In well-controlled studies on the effect of aorto-coronary bypass operations it has been confirmed

that this procedure is superior to any drug treatment in relieving angina pectoris. Moreover the objective effort tolerance of patients who have received the operation is higher than that of patients on drug treatment alone and the drug requirement of patients after aorto-coronary bypass is considerably lower than for medically treated subjects<sup>[1–3]</sup>.

On these observations there is general agreement. Controversy starts when this experience is being used in the decision making on how to treat a specific patient suffering from effort angina. Many clinicians support the view that a trial of drug treatment of several weeks or months should precede more specific investigation in all patients presenting with stable angina pectoris. This attitude is likely to reduce the number of angiographies and operative procedures, but we must also look at its drawbacks. During the delay a few patients will experience possibly avoidable coronary events such as myocardial infarction or sudden death. Many more will get used to their chronic condition. Their insecurity and fear of angina or worse make a change in their life style. If they become unemployed their daily schedule and activities will change. However, owing to their

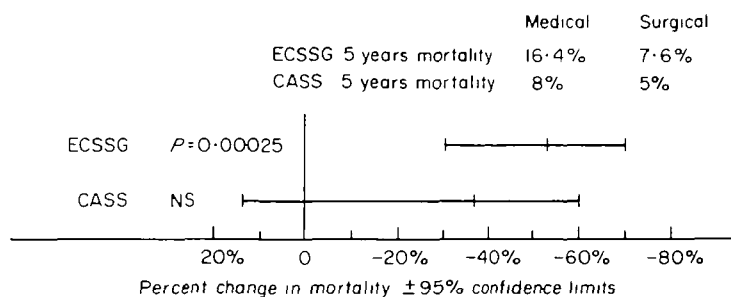


Figure 1 Effect of aorto-coronary artery bypass surgery on five-year survival in the prospective randomised ECSSG and CASS trials (m—multiple)

physical inactivity and to their drug regimen angina appears to improve. This may be satisfactory for many elderly subjects with a contemplative mode of life, but for a large number of patients, who experience angina pectoris in the middle of an active life, with family obligations, professional responsibilities or for enthusiastic sportsmen, such a passive attitude becomes unacceptable as soon as they learn of an alternative option promising return of previous physical ability without symptoms and a reduction of daily medication. For these patients a 6 to 8 month delay of active measures may irreversibly affect their psychological and economic future. There is obviously a wide range of subjective decisions to be made by the primary physician, which depends upon his expert assessment of the symptoms being presented, the general health status, and the personality of each individual patient. On the other hand, aorto-coronary bypass operations may prolong life in certain patients. This issue is most controversial because it has crucial consequences on the decision as to whether surgical treatment is superior to conventional management or not. The effect of aorto-coronary bypass has been studied by numerous investigators. In three large prospective trials selected patients were assigned at random to medical or surgical treatment and were closely followed afterwards<sup>[2,4,5]</sup>. In one of these studies carried out in Europe<sup>[2]</sup> it was found, that the operated patient group had a significantly better survival than the conventionally treated group. The more recent CASS study from the United States<sup>[5]</sup> showed no significant difference between surgically and non-surgically treated patients. However in this study all patients had an excellent prognosis. From the clinical trials we may conclude that the effect of aorto-coronary bypass on mortality depends on patient selection. It is obvious, that it is most difficult to improve

substantially a mortality rate which is very low. Julian has pointed out in a recent article on randomized trials, that the results of both the European and the CASS study are compatible (Fig. 1), the one showing a significant and the other an insignificant improvement of mortality. However the 95% confidence limits of both results show a considerable overlap. Most experts agree that there exist patients whose prognosis can be improved by aorto-coronary bypass. What we have to clarify more precisely, are the criteria to define patients at high risk, which can be improved by surgery. Thereafter large consecutive patient series including all aorto-coronary bypass operations performed at a centre should be analysed looking for the proportion of patients, whose prognosis is thought to be improved by surgery.

#### Alternative and complementary measures

Aorto-coronary bypass certainly is not a panacea against ischaemic heart disease and non-surgical therapy has not stood still. Changing habits may be responsible for the decreasing incidence of ischaemic heart disease in the United States. At least, stop smoking has been convincingly documented to reduce the mortality of patients with ischaemic heart disease. For other factors such as increased physical activity and change of dietary habits there is circumstantial evidence of benefit. However, all these mechanisms take considerable time to become manifest and to result in a substantial reduction of the number of patients with ischaemic heart disease.

Several drugs, such as beta-receptor-blocking agents, aspirin and possibly, calcium-channel inhibitors or lipid lowering substances may improve prognosis in subsets of patients with ischaemic heart disease. All these measures are not alternatives but complementary to ACBP surgery.

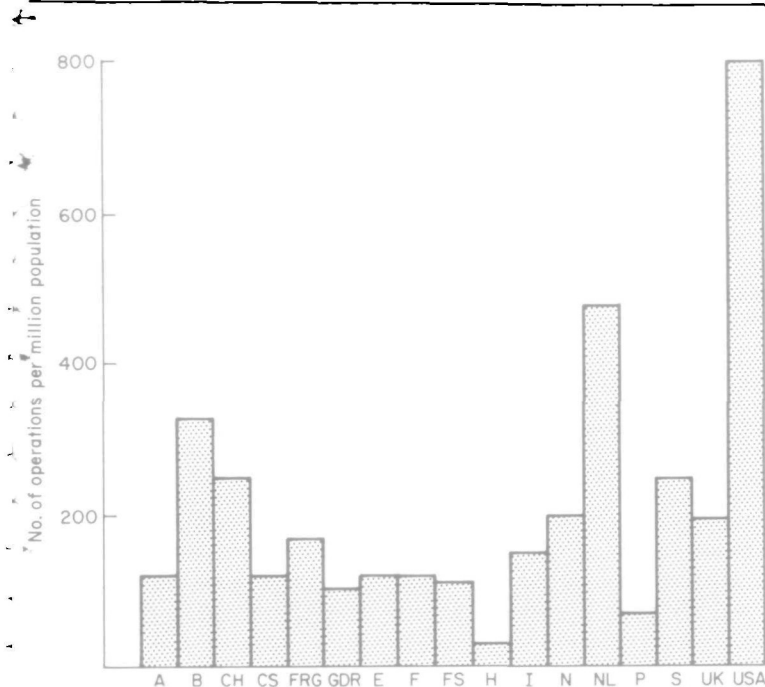


Figure 2 Number of aorto-coronary artery bypass operations performed in different European countries and in the U.S.A. during the year 1985.

The introduction of balloon dilatation of coronary obstructive lesions by Grüntzig, using a catheter system introduced percutaneously into the femoral artery may avoid surgical intervention. This procedure has gained wide application; its perfection and the additional use of laser techniques may avoid aorto-coronary bypass in selected patients. However, it is most likely that this measure will rather postpone than replace surgery in the majority of the candidates.

#### Cost of aorto-coronary bypass

The cost of aorto-coronary bypass surgery varies from one institution to another. The cost price of a bypass operation can only be estimated, because hospital charges do not necessarily reflect it. In the public medical system cost price seems to be about SFr 20 000, while it is SFr 30 000 for a private patient. The cost of preoperative diagnostic investigations is about SFr 3500 and 6000, respectively, for the public and private medical system. If postoperatively patients enrol in an institutional rehabilitation program, another SFr 5000 or 7000 have to be added resulting in a sum of SFr 28 500 and 43 000, respectively, for the two medical sys-

tems. Lichtlen estimates a similar cost of DM 50 000 per procedure in the F.R.G. while from the U.S.A. expenses around \$20 000 have been reported for the surgical procedure alone.

Last year about 250 operations were performed per one million population in Switzerland, assuming a price of SFr 40 000, about SFr 65 000 000 have been spent for aorto-coronary bypass corresponding close to 1% of the total expenses of the Swiss health insurance institutions and to less than 1/2% of the total expenses for health care.

#### Cost-benefit analysis

A cost-benefit analysis in the strict sense of the term seems to be most difficult for physicians because we cannot convert health care benefits into DM, £ or SFr. One way of assessment of cost-benefit ratio is analysing the return to work after aorto-coronary bypass. This problem has been thoroughly discussed during a symposium organized by the International and German Societies of Cardiothoracic Surgery two years ago<sup>[6]</sup>. Although many patients are enabled to resume their previous vocational activity after aorto-coronary bypass, there is considerable question as to this

benefit in most statistical studies on that subject. A major factor for not resuming gainful employment was found to be the delay in definite diagnosis, in taking the decision for angiography and surgery as well as the delay caused by waiting lists for diagnostic and therapeutic procedures.

### **Number of aorto-coronary bypass operations in European countries**

During a recent symposium in Salzburg, Unger collected figures on the number of bypass operations performed in European countries. It can be seen in Fig. 2, that these figures vary from 30 operations per year and one million inhabitants up to 475 in the Netherlands, as compared to 800 interventions per one million in the U.S.A. We have to keep in mind that the prevalence of ischaemic heart disease varies from country to country. Therefore it was proposed by the Dutch Heart Foundation to compare the number of operations per year with the corresponding mortality figures and it was found, that during 1982 in the United States the number of yearly operations corresponded to 31% of all subjects succumbing to ischaemic heart disease, in the Netherlands to 20%, in Switzerland to 12% and in the United Kingdom to 4% only. Such a difference in management is not only seen from one country to the other but may exist in each individual country as was observed in an ongoing study by Gutzwyler carried out on the number of coronary angiographies performed for each 100 000 residents of the 26 Swiss cantons<sup>[8]</sup>. In rural areas a much fewer number of patients undergo this diagnostic procedure than in urban agglomerations. Moreover more angiographies were performed in the South-western French speaking part as compared to the German speaking areas.

The trend of the numbers of aorto-coronary bypass at the University Hospital of Zürich shows a steady increase within the last decade, which is responsible for the total rise of heart surgery with extracorporeal circulation. Very similar observations have been made for the Netherlands and for the Federal Republic of Germany.

### **Factors influencing patient referral for aorto-coronary bypass surgery**

Before I estimate the number of aorto-coronary bypass operations for the nineteen nineties, I briefly review the factors influencing patient referral

in the future. Newly accepted indications for surgery, i.e. prompt operation in patients with suddenly aggravating angina pectoris and compatible angiographic findings will increase the number of operations. Improving operative experience results in a lower mortality and better success rate encouraging physicians to refer their patients for operation. Furthermore I have demonstrated that there are very considerable regional differences in patient referral and it may be expected, that more patients will be sent for invasive diagnostic study and surgery from areas, where for the time being patient management is most conservative. On the other hand, the declining incidence of ischaemic heart disease would be a factor reducing patient referral; however, such a favorable development has yet to occur in the European countries. Furthermore it remains to be shown, that newer therapeutic options such as balloon dilatation of coronary stenosis significantly reduce the number of bypass operations performed. Finally, there are economic factors influencing coronary artery surgery. Waiting lists for diagnostic investigations and surgical treatment result in a delay of 4–8 months in many heart surgical centres throughout Europe and discourage physicians from proposing surgical revascularisation to their patient. However to medical men seeking for the optimal treatment of their patients this attitude of deliberate restriction of treatment facilities is not an acceptable one. Nevertheless, a declining economical situation is an uncertain variable that might limit the feasibility of costly medical procedures in the future.

### **Anticipated number of aorto-coronary bypass operations**

For an assessment of the future development of aorto-coronary bypass in Switzerland I made an inquiry with heart surgeons and cardiologists at the five Swiss University Hospitals. Close to 250 operations per one million were performed in 1985. Asked for the anticipated number of bypass operations in the early nineties all heart surgeons and all but one cardiologists predict an increase from the present figures. The lowest estimate for the number of operations in the early nineties was 250 per one million while the majority of the answers indicate a lower limit of 350 operations. My personal prediction would be 350–400 operations per million and year and this seems to be compatible with the estimate of most of my medical and surgical colleagues.

## Summary

I have been solicited by the organizers not to present a final solution to the problem, but to comment on controversial issues.

For the indications for aorto-coronary bypass, consensus has been reached by most medical men that angina pectoris and, in selected patients, prognostic considerations are important. Controversy starts when we ask how much angina or what pattern of clinical and angiographic risk factors are required for the operative indication.

It remains to be seen, whether other forms of mechanical revascularisation, such as balloon dilatation can replace surgery in large numbers of patients, who are presently treated by aorto-coronary bypass.

An effort has been made by physicians to make greater use of cost-benefit analysis estimates in their medical decisions, and to provide policy makers with this information.

The number of aorto-coronary bypass operations in European countries varies considerably. The trend of these figures, however, is rising throughout Europe and therefore my personal answer to the crucial question in the title is: *expand*.

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## What will be the requirements for acute interventional procedures in Europe?

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The needs and the requirements are changing with such a pace that it is almost impossible to foresee what is going to happen within 5 years or even within 2 years. An inventory of interventional cardiac catheterization procedures (Table 1) shows that no. 1 is still percutaneous transluminal coronary angioplasty carried out by means of a balloon, a laser or by spark erosion<sup>[1,2]</sup>. These last two techniques are really to drill craters into atherosclerotic plaques. We believe that transluminal angioplasty will be necessary to keep the side-effects of these two powerful tools under control<sup>[3]</sup>.

Transluminal coronary recanalization and angioplasty in acute myocardial infarction, although extensively applied, is still under clinical investigation<sup>[4,5]</sup>. New techniques such as transluminal atherectomy have been recently introduced

and tested in human beings, but only on peripheral vessels<sup>[6]</sup>. For more than 10 years investigators have tried to supply the ischaemic myocardium with oxygenated blood through the coronary sinus<sup>[7]</sup>. Pulsatile retroperfusion of coronary sinus with oxygenated blood has been attempted in a few patients with unstable angina or during angioplasty. Intermittent coronary sinus occlusion seems to be another possible approach. Several percutaneous left ventricular assist devices are still under development; the most commonly used is intra-aortic balloon counterpulsation.

In 1984/1985 in Europe percutaneous balloon valvuloplasty began to be applied to acquired valvular disease. Congenital pulmonary stenosis was already an established indication when French cardiologists started to dilate calcified aortic valves